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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/521,730

01/20/2005

Robert John Noel

MCA-609 US

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MILLIPORE CORPORATION  
290 CONCORD ROAD  
BILLERICA, MA 01821

EXAMINER

SAUNDERS, DAVID A

ART UNIT

PAPER NUMBER

1644

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/521,730	<b>Applicant(s)</b> NOEL, ROBERT JOHN	
	<b>Examiner</b> David A. Saunders	<b>Art Unit</b> 1644	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 9/23/10.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-16, 18, 21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 12-16, 18, 21 and 22 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **AMENDMENT ENTRY**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/23/10 has been entered.

Following entry of the amendment of 9/23/10, claims 12-16, 18 and 21-22 are pending and are under consideration.

### **CORRECTIONS REGARDING PREVIOUS OFFICE ACTION**

The following corrections pertain to the previous Office action:

At page 8, 4<sup>th</sup> para., 2<sup>nd</sup> line thereof, "bound" should have read as --binds--.

At page 9, line 1, "1-2, 5, 7, 9 and 12" should have read as --1-2, 5, 7, 9-10 and 12--, since claim 10 was addressed further below.

### **OBJECTION(S)/REJECTION(S) OF RECORD WITHDRAWN**

The amendment has overcome previously stated issues as follows:

The objection to claim(s) 2 and 9 under 37 CFR 1.75.

The rejection of claim(s) 1-3, 5 and 7-14 under 35 USC 112, 2<sup>nd</sup> paragraph.

The rejection of claim(s) 19 under 35 USC 112, 1st paragraph, since claim 19 has been cancelled.

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The 102 prior art rejection of claim(s) 1-2 and 9-11 based upon Wu et al, since all rejected claims have been cancelled.

The 102 prior art rejection of claim(s) 1-2, 5, 7 and 9-14 based upon Lihme et al. Claims 1-2, 5, 7 and 9-11 have been cancelled. Independent claim 12 has been amended to require that the "second different ionic protein" is "protein A"; no such second protein is shown in the reference.

The 102/103 prior art rejection of claim(s) 12-14 based upon Hahn et al, since claim 12 has been amended to require that the "second different ionic protein" is "protein A"; no such second protein is shown in the reference.

The 102/103 prior art rejection of claim(s) 1-2, 5, 7, 9 and 12 based upon Graf et al. Claims 1-2, 5, 7 and 9 have been cancelled. Claim 12 has been amended to require that the "second different ionic protein" is "protein A"; no such second protein is shown in the reference.

All rejections of record in the action mailed on 3/19/10 have been overcome. However, upon reconsideration of applicant's entire disclosure, the following grounds of rejection are newly stated.

#### **NEW REJECTION(S) UNDER 35 USC 112, FIRST PARAGRAPH**

Claims 12-16, 18 and 21-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 12 and 15 do not recite all of the essential features of applicant's disclosed invention; as such, applicant is claiming new matter.

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More specifically, it is noted that the originally filed disclosure has repeatedly indicated that the invention is to be conducted without the provision/inclusion of any “added salt”/ “added ionic component” in the sample to be contacted with the cation-exchange adsorbent. Note, for example, the following sections of the disclosure:

The present invention is based on the realisation that, rather than using the combination of a high charge density adsorbent and added salt in the sample, desirable working capacity may be attained by varying the charge density of binding surfaces of the adsorbent. (p 3, lines 5-8).

According to the invention, a method of separating a selected ionic component from a sample, comprises contacting the sample with an ionic adsorbent whose charge density is such that the component is bound selectively, in the absence of an added ionic component that competitively binds the adsorbent. (p 3, lines 12-16).

the use of large quantities of additional salts is no longer necessary. (p 3, lines 24-25).

The invention bypasses the need for the inclusion of competing ionic components (e.g. salts) in the sample. (p 3, lines 31-32).

A method of separating a selected ionic component from a sample, which comprises contacting the sample with an ionic adsorbent whose charge density is such that the component is bound selectively in the absence of added ionic component that competitively binds the adsorbent. (orig. claim 1).

Since claims 12 and 15 are each open in scope, by virtue of the recitation of “comprising the steps of”, claims 12 and 15 could each be conducted with the practice of a prior step in which a “salt”/ “ionic component” is added to the sample that is to be contacted with the cation-exchange adsorbent. Since applicant’s original disclosure has emphasized that the invention is to be conducted without the inclusion of any “added salt”/ “added ionic component”, it is properly considered that applicant is reciting new matter, unless the practice of a prior step in which a “salt”/ “ionic component” is added to the sample is not negated/ruled-out.

Unfortunately for applicant, the Office can offer little in the way of suggestions as to how applicant may overcome this rejection without obscuring the nature of the claimed invention. It is to be noted that the Office has previously indicated (action of 5/14/07, at page 2) that:

In claim 1, the phrase “in the absence of added ionic component that competitively binds the adsorbent” is indefinite, because one does not know if a) the “added ionic component” is one the competes with the “selected ionic component” for binding to the adsorbent, b) the “added ionic component” is one the competes with some unrecited undesired/non-selected ionic component for binding to the adsorbent, or both a) and b).

This ground of rejection was again repeated in the action mailed on 2/13/08, at page 3. If applicant wants to enter a recitation like that recited in original claim 1, then applicant needs to make it clear what component the “added ionic component”/ “added salt” would compete with, if the “ionic component”/ “salt” had been added. The examiner presently considers that applicant may have intended to recite that the “added ionic component”/ “added salt” would compete the binding of an “undesired component” (now recited as “protein-A”) to the cation-exchange adsorbent? See BACKGROUND teachings at p 1, line 26. However, the filed disclosure is so brief that it lacks an adequate explanation concerning how “competitively binds” in original claim 1 has any nexus to what applicant has discussed in the BACKGROUND.

Additionally, if applicant wants to enter a recitation such as “in the absence of an added salt that binds the cation-exchange adsorbent”, then the phrase would be indefinite and it would not be supported. See action of 9/11/08, at page 3 and both the 112, 2<sup>nd</sup> and 112, 1<sup>st</sup> rejections therein stated. As noted under the stated 112, 1<sup>st</sup> rejection, the exemplified “sample” is not actually devoid of “added salt”, because the “sample” consisting of IgG and protein A was provided in a buffer of pH 4.0 to 4.5, and any buffer must inherently contain the positive ions of some “added salt”.

Furthermore, if applicant wants to enter a recitation such as “in the absence of an added salt that binds the cation-exchange adsorbent”, then the phrase would also be indefinite because one does not know what limitations are to be placed upon “added” in terms of the time-frame within which the salt could not be added. For example, if one elutes IgG from a protein-A column with an acidic buffer, then some salt that is inherently present in the eluting buffer gets “added” to the sample that is eluted from the Protein-A column. Perhaps applicant meant to recite that the salt would not be “added” to the eluate, once it has been obtained from the Protein-A column? However, applicant did not explicitly state so, and one is left to wonder. In the absence of any explicit statement in the disclosure, it would be new matter for applicant to presently clarify by stating just what time-frame is implied by “in the absence of an added salt”.

In summary, applicant is in a bind. It is new matter for applicant to not recite "in the absence of an added salt"; however, for applicant to recite "in the absence of an added salt" would lack disclosure support in the specification Examples, which used a buffer containing a salt. The invention has been described in such a sketchy manner, that one does not know what the meets and bounds would be of a chromatography method to be practiced "in the absence of an added salt". The invention has been described in such a sketchy manner, that one does not know how to practice a chromatography method to be conducted "in the absence of an added salt".

## **CONTACTS**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm and on alternate Fridays. The examiner's supervisor, Ram Shukla, can be reached on 571-272-0735. The fax number where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 11/30/10 DAS

/David A Saunders/

Primary Examiner, Art Unit 1644